IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC. and MAYNE PHARMA INTERNATIONAL PTY LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 13-2002-GMS
FOREST LABORATORIES, INC.,	)	
Defendant.	)	

ORDER

WHEREAS, the plaintiffs Teva Pharmaceuticals USA, Inc. and Mayne Pharma International Pty Ltd. (collectively, the Plaintiffs) filed this patent infringement action against the defendant Forest Laboratories, Inc. ("Forest"), alleging direct and indirect infringement of U.S. Patent No. 6,194,000 ("the '000 Patent") (D.I. 1);

WHEREAS, presently before the court is Forest's motion for judgment on the pleadings (D.I. 13);

WHEREAS, the court having considered the pleadings, the relevant documents, the parties' submissions, and the applicable law;

IT IS HEREBY ORDERED that:

Forest's Motion for Judgment on the Pleadings (D.I. 13) is DENIED.[1]

[1] The '000 Patent is entitled "Analgesic Immediate and Controlled Release Pharmaceutical Composition." (D.I. 1, Ex. A.) The Abstract states: "Disclosed is a method for the therapeutic treatment of pain related to wind up in a human or animal." (*Id.*) The '000 Patent contains forty-eight method claims, four of which are independent claims. Each of the independent claims includes references to an "analgesic pharmaceutical composition," containing N-methyl-D-aspartate ("NMDA") receptor antagonists in "sufficient amounts to diminish or abolish wind-up." *See* '000 Patent, claims 1, 7, 12, 44.

After having its New Drug Application approved by the FDA, Forest launched Namenda XR in the United States in 2013. (D.I. 1, ¶ 7.) Namenda XR is approved for the treatment of Alzheimer's disease. (D.I. 9, Ex. B.) The

Dated: March 25, 2015

UNITED STATES DISTRICT JUDGE

Plaintiffs allege that Namenda XR infringes the '000 Patent. Forest has moved to dismiss this action on the grounds that Namenda XR cannot infringe the '000 Patent as a matter of law because it is not approved to treat pain associated with wind up.

When deciding a Rule 12(c) motion for judgment on the pleadings based on an allegation that the plaintiff has failed to state a claim, the motion "is analyzed under the same standards that apply to a Rule 12(b)(6) motion." *Revell* v. *Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). That is, the court must view all facts and inferences drawn from the pleadings in the light most favorable to the non-moving party. *Green* v. *Fund Asset Mgmt., L.P.*, 245 F.3d 213, 220 (3d Cir. 2001). The issue for the court is "not whether the plaintiff will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims." *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974). As such, the touchstone of the pleading standard is plausibility. *Bistrian v. Levi*, 696 F.3d 352 365 (3d Cir. 2012). Plaintiffs must provide sufficient factual allegations "to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

Despite Forest's compelling arguments, the court cannot say—at this initial stage—that Namenda XR does not infringe the '000 Patent as a matter of law, even though its FDA-approved label does not include an indication for pain treatment (resulting from wind up, or otherwise). To be sure, pain treatment and wind up figure prominently in the '000 Patent claims. Nonetheless, the court is convinced that claim construction will resolve its outstanding questions as to whether these properties are absent from Forest's accused product or "coextensive with the FDA-approved label." *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1330 (Fed. Cir. 2012) (Newman, J., dissenting). Thus, the summary judgment process is more appropriate for addressing Forest's contentions.

Although it is close, the Federal Circuit's opinion in *Bayer* is distinguishable. First, as the Plaintiffs point out, *Bayer* dealt only with accused ANDA (abbreviated new drug application) products, rather than an already approved and marketed product like Namenda XR. *See id.* at 1319 (majority opinion) ("For method-of-use patents, the 'artificial' infringement claim provided by section 271(e)(2)(A) [infringement under the Hatch-Waxman Act] lies only against a patented use that has been approved by the FDA."). Second, the Federal Circuit acknowledged in *Bayer* that "the issue in these cases is a very narrow one." *Id.* at 1320. In particular, the dispute centered on what exactly the FDA had approved. *See id.* at 1320–21 ("Bayer's quarrel with the district court is limited to contending that the FDA *did* approve the use of Yasmin to obtain all three effects simultaneously in menopausal and premenopausal patients in need of all three effects, and that the defendants' ANDAs seek FDA approval for the same uses.")

At this time, the court is uncertain what elements of the '000 Patent are limiting or whether certain elements may be considered coextensive with the FDA label. Based on the information presently available, the court is satisfied that the Plaintiffs' allegations are sufficient to suggest a plausible inference of infringement.